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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/784,549

02/23/2004

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01-162US2

7760

27774 7590 02/03/2010

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EXAMINER

ABOAGYE, MICHAEL

ART UNIT

PAPER NUMBER

1793

MAIL DATE

DELIVERY MODE

02/03/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/784,549	<b>Applicant(s)</b> FLANAGAN, AIDEN	
	<b>Examiner</b> MICHAEL ABOAGYE	<b>Art Unit</b> 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 48-51 and 53-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48-51 and 53-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 48-51 and 53-69 are currently under consideration in the Application.

### ***Status of Previous Rejections.***

2. The previous rejection of claims 48-65 under 35 U.S.C. 103(a) by the combination of Applicant's Admitted Prior ART (AAPA), Hella et al. and Freedenberg et al. have been withdrawn based on the amendment to claim 48, and also Applicant's argument regarding substituting the scanning device of Hella for the galvanometer of Freedenberg is persuasive.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48-51 and 53-65 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of Flanagan (U.S. Patent No. 6696667) in view Hella et al. (US Patent No. 4,456,811) and Freedenberg et al. (US Patent No. 5,620,618).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they share the following common features: Laser cutting a tubular medical device generating a beam of radiation from a stationary radiation source; and directing the radiation beam onto the tubular workpiece by scanning the radiation beam so that a prescribed pattern is cut in the tubular workpiece; and for at least a portion of time during which the radiation beam is being directed, redirecting the radiation beam generated by the station radiation source so that it is scanned about a circumference of the tubular workpiece without rotation of the tubular workpiece. The instant claims 48-65 require a scanning galvanometer and a conical mirror having an aperture through which workpiece passes; U.S. Patent No. 6696667 uses pivoted scanning mirrors equivalent to scanning galvanometer, but fails to teach a conical mirror with apex aperture in the optical path.

Hella et al. teaches a method of laser heat treating a surface of a tubular workpiece by providing in the optical path of the laser beam a conical mirror having an apex with an aperture through which the workpiece passes relative to the laser beam (see, conical mirror 15 of figures 1 and 2); wherein said conical mirror focuses or directs

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the laser beams in a form of annular or ring-shape beams to scan and impinge circumferentially on the outer surface or the tubular workpiece; wherein said laser beams provide uniform and non-overlapping coverage with a predetermined width and energy profile over the surface of workpiece, thereby heat treating the surface to a uniform temperature and depth (Hella et al. abstract, column 4, lines 5-25, column 4, lines 63-65, column 5, lines 37-645, and figures 1 and 2).

Though Hella et al.'s method is not directed to laser cutting, however Freedenberg et al. teaches laser machining as known in the art to encompass all types of material processing or removal, either partially or through the workpiece to include cutting, drilling, heating, heat treating, material deposition, and the like (Freedenberg et al., column 12, lines 44-49). Therefore the same laser apparatus and method for heat treating a workpiece can be used for cutting a workpiece. On the basis of the teachings of Freedenberg et al., one of ordinary skill intending to cut or drill circumferentially uniform, and non-overlapping holes on an outer surface of a tubular workpiece would look to Hella et al., since the method of Hella et al. provides an improvement in the laser beam alignment and symmetry (see., Hella et al. column 6, lines 25-31). Furthermore the method of Hella et al. provides uniform and non-overlapping annular laser beam coverage over the surface of the workpiece. (Abstract, column 4, lines 1-25 and lines 59-65).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combined method of AAPA and Freedenberg et al. to provide in the optical path of the laser beam a conical mirror having aperture at the apex

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as taught by Hella et al. so that the stent or tubular workpiece can be moved relative to the laser beam by passing through the aperture of the conical mirror, thereby allowing uniform and non-overlapping holes to be cut or drilled circumferentially on an outer surface of the stent (see, Hella et al. (abstract, column 4., lines 1-25 and lines 59-65).

These claims 48-65 of the instant application is clearly coextensive with the scope of the claims 1-19 of U.S. Patent No. 6696667 as modified by the combination of Hella et al. Freedenberg et al.

4. Claims 66-69 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 U.S. Patent No. 6696667 in view of Freedenberg et al. (US Patent No. 5620618).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they share the following common features. Laser cutting a tubular medical device generating a beam of radiation from a stationary radiation source; and directing the radiation beam onto the tubular workpiece by scanning the radiation beam so that a prescribed pattern is cut in the tubular workpiece; and for at least a portion of time during which the radiation beam is being directed, redirecting the radiation beam generated by the station radiation source so that it is scanned about a circumference of the tubular workpiece without rotation of the tubular workpiece. The instant claims 66-69 require a scanning galvanometer, while U.S. Patent No. 6696667 uses pivoted scanning mirrors.

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Freedenberg et al. teaches a laser machining process by providing a movable pivoted mirrors or lenses (column 7, lines 60-64) or a galvanometer (Freedenberg et al., column 10, lines 11-28, column 11, lines 10-15, and column 59-67) for scanning the laser beam onto the surface of a workpiece.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of U.S. Patent No. 6696667 to use a galvanometer for scanning the laser beam as taught by Freedenberg et al. since pivoted mirrors or lenses and galvanometer alternative means known in the art for scanning laser beam, therefore substituting one alternative for the other would have only yielded a predictable result (Freedenberg et al., column 10, lines 11-28, column 11, lines 10-15, and column 59-67). These claims 66-69 of instant application is clearly coextensive with the scope of the claims 1-19 of U.S. Patent No. 6696667 as modified by Freedenberg et al.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 66-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Shapovalvo et al. (US Patent No. 6563080).

Regarding claim 66, Shapovalvo et al. teaches a method of manufacturing a medical device from a tubular workpiece (stent 247, figure 5) comprising: generating a

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beam of radiation from a stationary radiation source (abstract, and column 7, lines 46-50). Shapovalvo et al. also teaches applying the laser beam to cut a desired pattern in the stent preform by directing and redirecting the radiation beam (45a) by array of mirrors (column 3, lines 29-41); wherein the stent preform may be moved relative to the laser beam with the laser source being stationary or the laser beam may be moved relative to the stent preform and scan about a circumference of the stent (see, Shapovalvo et al. figure 5, column 2, lines 11-16, column 3, lines 29-40 column 5, lines 32-47 and column 7, lines 46-62); thus the option of the stent being stationary as in the instant amended claim 66 is not excluded. Note the examiner interprets scanning as traversing or sweeping, see Dictionary.com. (Evidence provided in the previous office action); also the Examiner equates the claims circumference of the tubular workpiece to the outer boundary or periphery of stent, see Dictionary.com.

Regarding claim 67, Shapovalvo et al. in figure 5 shows a scanned radiation beam within a planar scan area (circumferential surface of the stent), wherein the beam is incident at a 90° angle at the surface of the stent (note the laser beam impinges on the surface of the workpiece at an angle of 90 degrees).

Regarding claim 68, Shapovalvo et al. teaches a stent which is tubular (column, lines 13-14) and planar scan area that is perpendicular to a longitudinal axis of the tubular workpiece (figure 5).



***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior ART (AAPA), (Applicant's Specification, page I and figure 1) in view of Shapovalvo et al. (US Patent No. 6563080).

Regarding claim 66 AAPA teaches a method of manufacturing a medical device from a workpiece, comprising: generating a beam of radiation from a radiation source; AAPA , further teaches scanning the radiation impinging against the workpiece (Note that the examiner interprets scanning the radiation beam broadly as traversing or sweeping the radiation , see Dictionary.com). AAPA therefore broadly meets the scanning limitation since the radiation beam is caused to traverse over the workpiece to affect the prescribed cutting pattern). AAPA further teaches that the tube or stent (108) *may be rotated* via a rotational motor drive and linearly translated via linear motion (112), relative to a stationary laser source beam (See AAPA, specification page 1, lines 10-12). Therefore one reading this cited portion would readily appreciate that rotation of the workpiece in AAPA is optional.

AAPA fails to teach directing and redirecting the radiation beam onto the workpiece while the workpiece remains stationary.

Shapovalvo et al. teaches applying the laser beam to cut a desired pattern in the stent perform by directing and redirecting the radiation beam (45a) by array of mirrors (column 3, lines 29-41); wherein the stent preform may be moved relative to the laser beam with the laser source being stationary or the laser beam may be moved relative to the stent preform and scan about a circumference of the stent (see, Shapovalvo et al. column 5, lines 32-47). Therefore option of the stent or workpiece being stationary is not excluded in Shapovalvo et al.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify AAPA to direct and redirect the laser beam about the circumference of the stent by the stationary source while the workpiece is stationary, as said technique is known as an alternative to moving the stent relative to the a stationary laser beam as described by Shapovalvo et al. and doing so would have only yielded a predictable result.

Regarding claim 67, AAPA in figure 1 shows radiation beam that is scanned within a planar scan area throughout which the beam is incident at a 90° angle (note the radiation beam is incident on the workpiece at an angle of 90 degrees).

Regarding claim 68, AAPA in figure 1 shows planar scan area is perpendicular to a longitudinal axis of the tubular workpiece.

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9. Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior ART (AAPA), (Applicant's Specification, page I and figure 1) in view of Shapovalvo et al. (US Patent No. 6563080) as applied to claim 69 above and further in view of Freedenberg et al. (US Patent No. 5620618).

Regarding claim 69, AAPA and Shapovalvo et al. teach scanning the laser beam over the surface of the workpiece but do not particularly teach scanning with a galvanometer.

Freedenberg et al. teaches a laser machining process by providing pivoted and movable mirrors or lenses (column 7, lines 60-64) or a galvanometer (Freedenberg et al., column 10, lines 11-28, column 11, lines 10-15, and column 59-67) for scanning the laser or radiation beam.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combined invention of AAPA and Shapovalvo et al. to use a galvanometer for scanning the laser beam as taught by Freedenberg et al. since an assembly of movable pivoted mirrors or lenses and galvanometer are known alternative laser or radiation scanners known in the art, therefore substituting one alternative for the other would have only yielded a predictable result (Freedenberg et al., column 10, lines 11-28, column 11, lines 10-15, and column 59-67).

#### ***Allowable Subject Matter***

10. Claims 48-51 and 53-65 would be allowable if a Terminal disclaimer is filed to overcome nonstatutory obviousness-type double patenting.

The following is a statement of reasons for the indication of allowable subject matter: Though the elements of claim 48 as amended are substantially taught by the combination of AAPA, Hella et al. and Freedenburg, however modifying AAPA and Hella et al. by replacing the scanning arrangement in Hella et al. with the galvanometer of Freedenburg would not yield the expected result, therefore one of ordinary skill in the art would not be motivated to make said modification. The combination of AAPA, Hella et al. and Freedenburg, therefore fail to render claim 48 obvious.

### ***Response to Arguments***

11. Applicant's arguments filed 11/03/2009 have been fully considered but they are not persuasive.

With respect to claims 66-69 as amended, Applicant urges that the claim requires the radiation beam to be is redirected so that it is scanned about a circumference of the tubular workpiece while the tubular workpiece remains stationary, and also requires the beam to be scanned about the circumference of the tubular workpiece without movement of either the radiation source or the workpiece, and in contrast to the invention AAPA and Shapovalvo, which can only scan the beam around the circumference of the workpiece when there is some relative movement between the workpiece and the radiation source.

In response, the Examiner disagrees, because Shapovalvo et al. applies the laser beam to cut a desired pattern in the stent preform by directing and redirecting the radiation beam (45a) by array of mirrors (column 3, lines 29-41); and states that the

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stent preform may be moved relative to the laser beam with the laser source being stationary or the laser beam may be moved relative to the stent preform and scan about a circumference of the stent (see, Shapovalvo et al. column 5, lines 32-47). Therefore option of the stent or workpiece being stationary is not excluded in Shapovalvo et al. The 35 U.S.C. § 102(b) rejections of claims 66-68 by Shapovalvo and 35 U.S.C. § 103(a) rejections of claims 66-69 by the combination of AAPA, Shapovalvo and Freedenberg shall remain.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL ABOAGYE whose telephone number is (571)272-8165. The examiner can normally be reached on Mon - Fri 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jessica Ward can be reached on 571-272-1223. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. A./  
Examiner, Art Unit 1793

/Jessica L. Ward/  
Supervisory Patent Examiner, Art Unit 1793